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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,394	06/02/2005	Francois Romagne	INN-123	8478

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EXAMINER	
TEALE, MICHAEL J	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
08/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,394	ROMAGNE ET AL.	
	Examiner	Art Unit	
	Michael J. Teale	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *80-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. The inventions listed as claims 80-101 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. In Kunzman *et al.*, teaches compositions containing a γδ-cell activator to generate antiplasma cell activity in multiple myeloma (see abstract).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: cancer, solid tumors, infectious diseases, autoimmune diseases and allergic disease; furthermore, applicant should identify a specific disease, for example genus of infectious diseases includes all disease associated with infectious organisms and virus. It is very unlikely that applicant's invention would be effective against all infectious diseases.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. **The reply must also identify the claims readable on the elected species, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Election Requirement

3. The claims encompass hundreds of different compounds (as claimed: for example see broad structures in claims 91, 92, and 96), which are contained in many different compositions. The compounds vary distinctly in their structures and functions. Thus, an individual search is required of each individual compound. Therefore, applicant is required to elect a specific compound to which the examination will be limited unless that compound cannot be found in the art and in that case a reasonable core structure (based on the elected compound) will be searched; as well as identifying those claims to which the elected compound is drawn. This requirement is *not* to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Teale whose telephone number is (517)272-6897. The examiner can normally be reached on 9:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL MELLER
PRIMARY EXAMINER

10/537394
JC17 Rec'd PCT/PTO 02 JUN 2005

In the Claims

Claims 1-79 (Canceled).

Claim 80 (New): A method of treating a disease comprising the administration of a composition γδ cell activator comprising a pharmaceutically acceptable carrier in an amount sufficient to induce an at least 5-fold increase in the γδ T cell population in a subject, wherein said disease is selected from the group consisting of cancer, solid tumors, infectious diseases, autoimmune diseases and allergic disease.

Claim 81 (New): The method according to claim 80, wherein said γδ T cell activator is provided in an amount sufficient to induce an at least 10-fold increase in the γδ T cell population in a subject.

Claim 82 (New): The method according to claim 80, wherein at least two treatments are administered to said subject.

Claim 83 (New): The method according to claim 80, wherein at least four treatments are administered to said subject.

Claim 84 (New): The method according to claim 80, wherein the γδ T cell activator is administered in more than one treatment with an interval of about two to about eight weeks between treatments.

Claim 85 (New): The method according to claim 80, wherein the γδ T cell activator is administered in more than one treatment with an interval of about three to about four weeks between treatments.

Claim 86 (New): The method according to claim 80, wherein said γδ T cell activator is provided in an amount sufficient to expand the γδ T cell population in a subject to reach between 30-90% of total circulating lymphocytes in a subject.

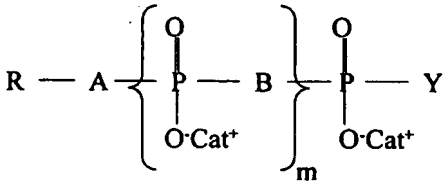
Claim 87 (New): The method according to claim 80, wherein the biological activity of γδ T cells are increased in said subject.

Claim 88 (New): The method according to claim 80, wherein the solid tumor is renal cancer.

Claim 89 (New): The method according to claim 80, wherein said solid tumor is selected from the group consisting of a melanoma, ovarian cancer, colon cancer, lung cancer, pancreatic cancer, neuroblastoma, head or neck cancer, bladder cancer, breast cancer, brain cancer and gastric cancer.

Claim 90 (New): The method according to claim 80, wherein the γδ T cell activator is a composition comprising a compound capable of inducing the proliferation of a γδ T cell in a pure population of γδ T cell clones when said compound is present in culture at a concentration of less than 1 mM.

Claim 91 (New): The method according to claim 80, wherein the γδ T cell activator is a compound of formula (I):



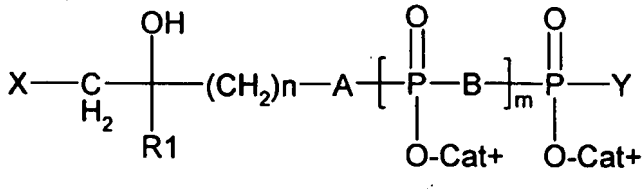
Formula (I)

wherein Cat+ represents at least one organic or mineral cation that can be the same or different;
m is an integer from 1 to 3;
B is O, NH, or any group capable of being hydrolyzed;
Y = O⁻Cat+; a C_1-C_3 alkyl group; -A-R; or a radical selected from the group consisting of a nucleoside, an oligonucleotide, a nucleic acid, an amino acid, a peptide, a protein, a monosaccharide, an oligosaccharide, a polysaccharide, a fatty acid, a simple lipid, a complex lipid, a folic acid, a tetrahydrofolic acid, a phosphoric acid, an inositol, a vitamin, a co-enzyme, a flavonoid, an aldehyde, an epoxyde and a halohydrin;

A is O, NH, CHF, CF_2 or CH_2; and,

R is a linear, branched, or cyclic, aromatic, non-aromatic, saturated or unsaturated C_1-C_{50} hydrocarbon group, optionally interrupted by at least one heteroatom, wherein said hydrocarbon group comprises an alkyl, an alkylenyl, an alkynyl or an alkylene, which can be substituted by one or several substituents selected from the group consisting of: an alkyl, an alkylenyl, an alkynyl, an epoxyalkyl, an aryl, an heterocycle, an alkoxy, an acyl, an alcohol, a carboxylic group (-COOH), an ester, an amine, an amino group ($-NH_2$), an amide ($-CONH_2$), an imine, a nitrile, an hydroxyl (-OH), a aldehyde group (-CHO), a halogen, a halogenoalkyl, a thiol (-SH), a thioalkyl, a sulfone, a sulfoxide, and a combination thereof.

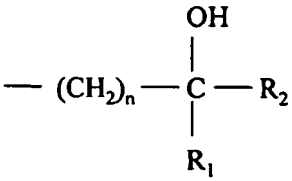
Claim 92 (New): The method according to claim 91, wherein the γδ T cell activator is a compound of formula (II):



(II)

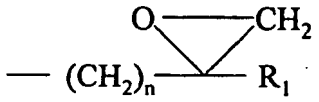
in which X is an halogen, B is O or NH, m is an integer from 1 to 3, R1 is a methyl or ethyl group, Cat+ represents at least one organic or mineral cation, n is an integer from 2 to 20, A is O, NH, CHF, CF_2 or CH_2, and Y is O^-Cat+, a nucleoside, or a radical –A-R, wherein R is selected from the group consisting of:

1)



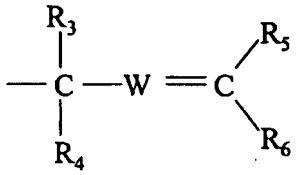
wherein n is an integer from 2 to 20, R_1 is a (C_1-C_3)alkyl group, and R_2 is an halogenated (C_1-C_3)alkyl, a (C_1-C_3)alkoxy-(C_1-C_3)alkyl, an halogenated (C_2-C_3)acyl or a (C_1-C_3)alkoxy-(C_2-C_3)acyl;

2)



wherein n is an integer from 2 to 20, and R_1 is a methyl or ethyl group; and

3)



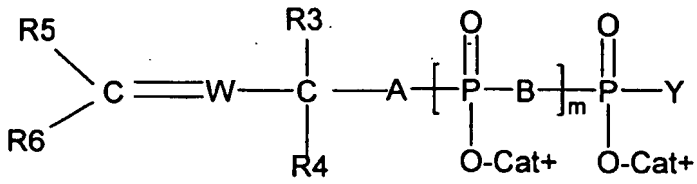
wherein R_3, R_4, and R_5 are identical or different and are a hydrogen or $(C_1$-$C_3)$alkyl group, W is –CH- or –N- and R_6 is an $(C_2$-$C_3)$acyl, an aldehyde, an $(C_1$-$C_3)$alcohol, or an $(C_2$-$C_3)$ester.

Claim 93 (New): The method according to claim 92, wherein the compound of formula (II) is (R, S)-3-(bromomethyl)-3-butanol-1-yl-diphosphate.

Claim 94 (New): The method according to claim 92, wherein the γδ T cell activator is administered in a dose to humans between 10 mg/kg to 100 mg/kg.

Claim 95 (New): The method according to claim 92, wherein said γδ T activator is administered by intravenous infusion in a dose to humans that is calculated according to the formula (I): single dose (mg/kg)=(10 to 100) * N (I), where N is the number of weeks between treatments such that N is between about 3 and about 4.

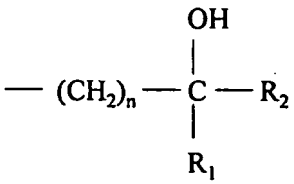
Claim 96 (New): The method according to claim 91, wherein the γδ T cell activator is a compound of formula (XII):



(XII)

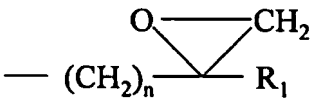
in which R_3, R_4, and R_5 are identical or different and are a hydrogen or $(C_1$-$C_3)$alkyl group, W is –CH- or –N-, R_6 is an $(C_2$-$C_3)$acyl, an aldehyde, an $(C_1$-$C_3)$alcohol, or an $(C_2$-$C_3)$ester, Cat+ represents at least one organic or mineral cation that can be the same or different, B is O or NH, m is an integer from 1 to 3, A is O, NH, CHF, CF_2 or CH_2, and Y is O^-Cat+, a nucleoside, or a radical –A-R, wherein R is selected from the group consisting of:

1)



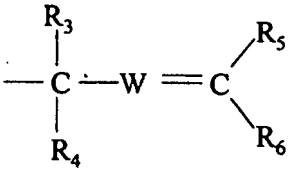
wherein n is an integer from 2 to 20, R_1 is a $(C_1$-$C_3)$alkyl group, and R_2 is an halogenated $(C_1$-$C_3)$alkyl, a $(C_1$-$C_3)$alkoxy-$(C_1$-$C_3)$alkyl, an halogenated $(C_2$-$C_3)$acyl or a $(C_1$-$C_3)$alkoxy-$(C_2$-$C_3)$acyl ;

2)



wherein n is an integer from 2 to 20, and R_1 is a methyl or ethyl group; and

3)



wherein R_3, R_4, and R_5 are identical or different and are a hydrogen or $(C_1$-$C_3)$alkyl group, W is CH or N, and R_6 is an $(C_2$-$C_3)$acyl, an aldehyde, an $(C_1$-$C_3)$alcohol, or an $(C_2$-$C_3)$ester.

Claim 97 (New): The method according to claim 96, wherein the compound of formula (XII) is (E)-4-hydroxy-3-methyl-2-butenyl pyrophosphate.

Claim 98 (New): The method according to claim 96, wherein the compound of formula (XII) is (E)-5-hydroxy-4-methylpent-3-enyl pyrophosphonate.

Claim 99 (New): The method according to claim 96 where said γδT activator is administered by intravenous infusion in a dose to humans that is calculated according to the formula (I) single dose (mg/kg)=(0.01 to 20) * N (I) where N is the number of weeks between treatments such that N is between about 3 and about 4.

Claim 100 (New): The method according to claim 80, further comprising separately administering to a subject in need thereof an effective amount of a γδT activator and an interleukin-2 polypeptide.

Claim 101 (New): The method according to claim 100, wherein the interleukin-2 polypeptide is administered over a period of time comprised between 1 and 10 days.